PCT/GB04/02531

INVESTOR IN PEOPLE

The Patent Office
Concept House
Cardiff Road
Newport
South Wales
NP10 8QQ

PRIORITY DOCUMENT

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

I, the undersigned, being an officer duly authorised in accordance with Section 74(1) and (4) of the Deregulation & Contracting Out Act 1994, to sign and issue certificates on behalf of the Comptroller-General, hereby certify that annexed hereto is a true copy of the documents as originally filed in connection with the patent application identified therein.

I also certify that the application is now proceeding in the name as identified herein.

I also certify that the attached copy of the request for grant of a Patent (Form 1/77) bears an amendment, effected by this office, following a request by the applicant and agreed to by the Comptroller-General.

In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

In accordance with the rules, the words "public limited company" may be replaced by p.l.c., plc, P.L.C. or PLC.

Re-registration under the Companies Act does not constitute a new legal entity but merely subjects the company to certain additional company law rules.

Signed Stephen Hordley

Dated 17 September 2004

GB 0313445.9

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of:

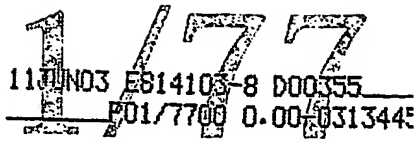
T.J. SMITH & NEPHEW LIMITED,
P.O. Box 81,
101 Hessle Road,
KINGSTON-UPON-HULL,
HU3 2BN,
United Kingdom

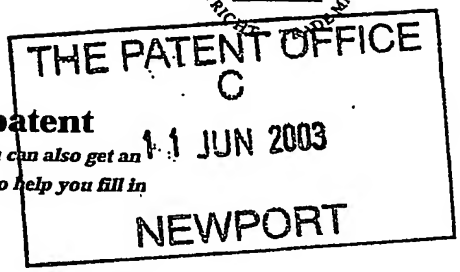
Incorporated in the United Kingdom,

[ADP No. 08912677001]

Patents Form 1/77

Patents Act 1977
(Rule 16)





Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
Newport
South Wales
NP10 8QQ

1. Your reference — M072217PGB

2. Patent application number *(The Patent Office will fill in this part)* — 0313445.9 — 11 JUN 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

MIDLAND MEDICAL TECHNOLOGIES LIMITED
Birmingham University Research Park
Vincent Drive
Edgbaston, BIRMINGHAM B15 2SQ

11/6/04

SECTION 30 (1977 ACT) APPLICATION FILED

Patents ADP number *(if you know it)* 8543597002

If the applicant is a corporate body, give the country/state of its incorporation — GREAT BRITAIN

4. Title of the invention — HIP RESURFACING

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

~~Marks & Clerk~~
~~Alpha Tower~~
~~Suffolk Street Queensway~~
~~Birmingham B1 1TT~~

Martin Connors
Patent & Trade Mark Department
Smith & Nephew plc
Research Centre
York Science Park
Heslington, York
YO10 5DF

Patents ADP number *(if you know it)* ~~18002~~

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*
		P51/77 7/6/04

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

YES

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	13
Claim *(s)*	
Abstract	
Drawing *(s)*	1 + 1

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature

Date 10 JUNE 2002

12. Name and daytime telephone number of person to contact in the United Kingdom

STEPHEN G MOSEY
0121 643 5881

Warning

After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 08459 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

f) For details of the fee and ways to pay please contact the Patent Office.

HIP RESURFACING

This invention relates to hip resurfacing generally, and in particular to a method and apparatus for improving the accuracy of installation of a prosthetic hip resurfacing device (femoral component).

In the resurfacing of a patient's hip, installation of the resurfacing device requires that a guide wire for a drill is installed on a chosen axis of the head/neck of the patient's femur. The chosen axis is identified by the Surgeon through analysis of X-ray or similar technique. Prior to the fitting of the resurfacing device, the femoral head will be machined to a cylindrical shape, and since the axis of this is determined by the drill guide wire, it is important that the guide wire is accurately located, so that the resurfacing device itself can subsequently be accurately fitted.

An object of the invention is to provide a method and apparatus for improving the accuracy of installation of a prosthetic hip resurfacing device.

According to a first aspect of the invention, guide wire location means for locating, in use, a guide wire at an axis of a neck of a patient's femur comprises a base part for securement to a head of the femur, a part securable to the base part and spherically adjustable relative thereto, a part for directly or indirectly receiving a wire guide, and arranged for planar adjustment, said wire guide receiving part being securable to said spherically adjustable part, and sighting means including a probe having a part engagable with the head and/or neck of the femur.

The sighting means includes a sighting element such as a disc, which is the same size as the interior of a cylindrical saw cutter which will machine the head. By the use of the probe, the surgeon can gauge where the saw cutter will pass when it moves along the axis the guide wire defines. If the saw would cut the femoral neck, and not the head alone, the wire guide receiving part is adjusted accordingly and the sighting repeated until the axis is correct.

According to a second aspect of the invention, there is provided a method of locating a guide wire at an axis of a neck of a patient's femur using guide wire location means of said first aspect of the invention, the method comprising securing said base part to the head of the femur at approximately said axis, appropriately adjusting the attitude of said spherically adjustable part prior to fitting thereto said wire guide receiving part, fitting said wire guide receiving part to said spherically adjustable part, setting its planar position and subsequently adjusting same if necessary in response to engagement of said part of the probe means with the head or neck of the femur, and inserting said guide wire directly or indirectly into the wire guide receiving part upon any adjustment of its planar position having been completed.

The invention will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a sectional side view of guide wire location means of one aspect of the invention in use in a method of accurately locating the guide wire in a chosen axis of a neck of a patient's femur, which method forms another aspect of the invention,

Figure 2 is an exploded perspective view of Figure 1, and

Figures 3 and 4 are respectively views corresponding to Figures 1 and 2 for a second embodiment of said guide wire location means and a second embodiment of said method respectively.

As described in the introduction, it is important with hip resurfacing that the guide wire for the drilling of the head of the femur is accurately located, and the present invention seeks to improve this accuracy as compared to what is presently known. Figures 1 and 2 relate to a first embodiment of guide wire location means of the invention and will be described in relation to the method of operation, whilst Figures 3 and 4 show a second embodiment of the guide wire location means and will be described by way of a second method of operation, the invention residing both in relation to the guide wire location means itself, and also separately to the method of operation, in each case.

With regard to the first embodiment shown in Figures 1 and 2, the guide wire location means 10 comprises a base part which includes three identical circular plates 11, 12, 13 respectively, each plate having a central circular hole and, in the annular surface therearound, three equi-angularly spaced smaller circular threaded holes 14, 15, 16 respectively. The three plates are placed together with the three larger holes aligned and additionally with each of the smaller holes aligned with one of the smaller holes in the other of the two plates. The base part also includes three headed studs 17, 18, 19 respectively which have pointed ends remote from their respective heads, the respective bodies of the studs

extending from the heads having a fine thread therealong. These studs are screwed into the respective aligned holes in the three plates 11, 12, 13 as shown for stud 17 in Figure 1 with its point extending below the lowermost plate 13.

An enclosure 20 has a cylindrical lower portion 21 and a part-spherical upper portion 22, the upper portion having a central circular opening 23 therethrough. The wall thickness of the enclosure 20 is slightly greater with the lower portion 21 than the upper portion 22, but at its open end the interior of the lower portion 21 is outwardly stepped to provide an annular groove so that the assembly of the three plates 11, 12, and 13 can be located inside this open end of the cylindrical lower portion 21, as shown in Figure 1. At the exterior of the position of this grove, there is provided a short, internally threaded boss 24 for receiving a locking screw 25.

Received within the enclosure 20 is an adjustment member 26 which has a generally cylindrical lower part 27 with a part spherical upper surface 28 which substantially matches the interior part-spherical surface of the portion 22 of the enclosure 20. From the centre of this upper surface 28 extends a hollow cylindrical boss 29 which projects through the opening 23 at the top of the enclosure 20 with clearance, in order to allow spherical adjustment motion of the adjustment member 26 within the enclosure 20. Three equi-angularly spaced slots are formed in the lower part 27 of adjustment member 26, these slots extending partly through the upper surface 28. Two of these slots 30, 31 are shown in Figure 2. On the upper part of the part-spherical exterior surface of the enclosure 20 is a circular lock ring 32. This has an exteriorly knurled outer cylindrical part

33, from which extends inwardly a domed portion 34 having a lower, part-spherical undersurface 35 which matches the part-spherical exterior surface at the top of the portion 22 of the enclosure 20. This portion 34 has a central circular hole 36 therein in which the boss 29 is a close fit, with external screw threads on this boss engaging with internal screw threads in the hole 36 so that the lock ring 32 can be screwed to the boss 29, and thus to the adjustment member 26 so as to draw the part-cylindrical surfaces of the member 26 and the lock ring 32 against the cooperating inner and outer part-spherical surfaces respectively of the adjustment member 26 as shown in Figure 1. The three studs 17 to 19 are received respectively in the three slots in the bottom of the adjustment member 26 with clearance, to allow articulation, but preventing rotation while tightening the lock ring 32.

As can be seen from Figure 1, the boss 29 extends through the hole 36 of the portion 34 of the lock ring 32 and has received therein a cannula guide 37 which is the form of an elongated cylindrical body having an external circular flange 39 perpendicular thereto adjacent a reduced diameter end of the body. A fine circular bore 40 extends through the cannula guide 37 for the insertion of the guide wire for a drill (not shown) mentioned above. As shown in Figure 1, the flange 39 rests on the top of the boss 29 with the reduced diameter lower part of the cannula guide being received in the interior of the boss with significant clearance so that the planar position of the cannula guide can be readily adjusted.

The cannula guide can be locked in position by a further circular lock ring 41 which, like the lock ring 32 has a knurled exterior surface. The further lock ring 41 is generally hollow and has its lower end open, with its

exterior surface at said lower open end being externally threaded to engage with complimentary internal threads on the part 33 of the lock ring 32. As shown in Figure 1, when the lock ring 32 and the further lock ring 41 are screwed together, the underside of an annular top flange 42 of the further circular lock ring 41 engages against the upper surface of the flange 39 to hold the cannula guide 37 in its adjusted position by virtue of it being forced tightly against the top of the boss 29.

The centre of the flange 42 of the further lock ring 41 is provided with a central circular bore, this extending upwardly through an outwardly lipped boss 44, the annular lip 45 being spaced from, but extending parallel to, the top flange 42 of the further lock ring 41.

Fitted on top of the lip 45 with the body 38 of the cannula guide 37 extending closely through a central circular hole thereof is a sighting disc 47. This thus defines between itself and the upper surface of the flange 42 a stepped annular slot 48. The sighting disc 47 is the same size as the cylindrical saw cutter that will machine the femoral head.

Inserted into this slot is a slider 49 which has an inner portion 50, of the same curvature as the boss 44 and lip 45, and from which extends a pair of spaced parallel arms 51, 52 respectively. The respective interior surfaces of the portion 50 and the arms 51, 52 are configurated to match the shape of the stepped slot, and the spacing of the arms is such that they engage diametrically opposed surfaces respectively of the lipped boss 44 so that the slider can be rotated around the boss. Finally as far as the structure of the guide wire location means is concerned, an extension part 53 of the slider at the opposite side of the portion 50 from that at which

the arms extend, is provided with a through hole in which is slidably adjustable rod-like XY probe 54 which with the disc 47 constitutes sighting means of the device. At its lower end the probe is formed with a generally semi-circular contact member 55 arranged to engage the exterior surface of the head of a patient's femur 56. The probe, in conjunction with the sighting disc 47, enable the Surgeon to gauge where the saw cutter will pass when it moves along the axis that the guide wire defines.

The guide wire location means described above is used as follows.

Firstly, the Surgeon rests the base part, comprising the three plates 11 to 13 and the three studs 17 to 19, on the head of the femur as shown in Figure 1, the three plates being engaged together and the three studs each being screwed into one of the three series of three aligned holes in the plates respectively. Initially this positioning of the base part on the head of the femur is such that it lies approximately on the chosen axis of the neck of the femur. A cylindrical drift tool (not shown) is then located into the central aligned larger holes of the plates of the base part and is used to drive the assembly of the plates and the studs into the surface of the bone of the femoral head, thereby securing it in position.

The enclosure 20, adjustment member 26 and lock ring 32 are then fitted as an assembly, with the enclosure being fitted to the base part and secured by the locking screw 25 as shown in Figure 1, the three plates 11 to 13 which are engaged together, being received in the outwardly-stepped groove at the interior of the lower end of the enclosure 20. The lock ring 32, when unscrewed relative to the adjustment member 26, will allow spherical motion of the adjustment member 26 and lock ring 32

relative to the enclosure which is fast with the base part. Thus the Surgeon can choose the correct angular position of the jig, prior to fitting the cannula guide 37.

To optimise the angular position of the adjustment member 26, the surgeon can fit a protractor and probe device (not shown) into the bore in the boss 29 of the adjustment member and resting on its top surface. This can be used to provide correct angular alignment in both planes using pre-selected features on the femur. When satisfied that the angular alignment is correct, the Surgeon tightens the lock ring 32, with the result that the adjustment member 26 can no longer articulate. It will be noted that the three slots in the adjustment member 26, in which are received the studs 17 to 19 respectively, prevent the adjustment member 26 from rotating about the centre line of the jig during tightening, but still allow articulation of the adjustment member 26 relative to the enclosure.

The Surgeon then fits the cannula guide 37, the further lock ring 41 and the sighting disc 47 as shown in Figure 1. As stated, the sighting disc is the same size as the hollow cylindrical saw cutter and thus represents the final machine diameter of the femoral head prior to the fitting of the resurfacing device. The Surgeon then slides the slider 49 and the XY probe 54 into position so that the contact member 55 touches the high point of the head of the femur, as shown in Figure 1. The Surgeon is thus able visually to judge the position of the sighting disc/cannula guide relative to a sighting mark on the top surface of the slider. This allows the Surgeon then, if necessary, to adjust the cannula guide in a single plane, by slackening the further lock ring 41 and incrementally moving the cannula guide. The slider can then be rotated in its slot 48 in order to

make similar adjustments in alternative planes. These alternative planes lie through the axis of the cannula guide, i.e. the Surgeon rotates the probe 54 around the femoral head/neck, testing the XY position of the cannula guide in various vertical planes, 'vertical' meaning along the axis of the cannula guide.

It is important that whilst the femoral head is cut, to a cylindrical shape, the femoral neck/stem below the head is not cut, since this could lead to weakening thereof. Thus having fixed the position of the cannula guide, the Surgeon would probe the head of femur at various heights depending on the shape and degree of malformation – each time comparing the resting position of the probe against the head/neck of the femur with the sighting disc 47 (representing the cylindrical saw cutter that would subsequently be used). In this way he is able to predict where material would be removed and where there would be clearance from the cutter. Thus he can decide if adjustment of the guide 37 is required.

Finally when satisfied with the rotational and planar positioning of the cannula guide 37, the surgeon fixes its position by screwing up the further lock wing 41 so that the arrangement shown in Figure 1 is reached with the cannula guide held in position between the flange 42 and the top of the boss 29. The insertion of the guide wire using the central hole in the cannula guide as a location can then proceed, with this now being set very accurately so that subsequently the drilling of the femur head is similarly of improved accuracy and is thus at the chosen axis previously identified by the Surgeon through analysis of X-ray or similar technique.

In the second embodiment shown in Figures 3 and 4, the adjustable base part of the first embodiment is replaced with a one-piece base part 57 in the form of an annulus having an exterior cylindrical surface 58 and a part-spherical upper surface 59. Spikes 60 extend from the underside of the surface 58 to be equivalent to the points provided by the studs 17 to 19 of the first embodiment. The annulus defines a central circular opening 61 and the interior surface of this opening can be slightly tapered as shown in Figure 3. This base part 57 will be manufactured in such a manner as to allow the insertion of a Ferro-magnetic core, contained within a Medical Stainless Steel exterior.

Received in engagement with the part 57 on the upper part-spherical surface 59 thereof is an adjustment member 62 which is effectively equivalent to the assembly of the first embodiment formed by the enclosure 20, the adjustment member 26 and the lock ring 32. This adjustment member 62 is basically in the form of a circular annulus having a central circular opening 63 therethrough. The member 62 has its lower surface 64 of part spherical form to match the part-spherical upper surface 59 of the base part 57 to allow spherical adjustment motion as with the first embodiment. The external cylindrical surface of the annular adjustment member 62 is formed with a rectangular annular groove 65. The adjustment member 62 will, like the base part 57, be manufactured in such a manner as to allow the insertion of magnetic material into a Medical Stainless Steel exterior. Accordingly when placed onto the base part 57, the adjustment member 62 will magnetically adhere to the part-spherical surface thereof as shown in Figure 3.

A cannula guide 66 of this second embodiment is of similar form to cannula guide 37 of the first embodiment, but does not have its body continuing below the circular exterior flange which in Figures 3 and 4 is denoted by the numeral 67. Moreover the bore 68 through the guide 66, is no longer fine but is widened to receive an elongated pivot rod 69 therethrough, the rod 69 having a fine bore 70 therethrough for the insertion of the guide wire. The lower end of the pivot rod 69 , which extends below flange 67, is barbed or similarly configured so that it can be pushed into the surface of the bone of the femur head to provide additional support as shown in Figure 3. The cannula guide will be manufactured in such a manner so as to allow the insertion of a Ferro-magnetic core, contained within a Medical Stainless Steel exterior. Thus when placed on the top of the adjustment member 62, the cannula guide will magnetically adhere to the planar surface thereon as shown in Figure 3, with the opening 63 in the member 62 and the opening 61 in the part 57 being greatly oversized relative to the diameter of the pivot rod so as to allow for planar adjustment, as with the first embodiment, of the cannula guide, and thus the pivot rod.

With this second embodiment, as with the first embodiment, a slider 71 of similar form to the slider 49 of the first embodiment, has its arms 72, 73 respectively received in and above the groove 65 formed in the adjustment member 62 so that diametrically opposed inner surfaces of the groove 65 engage respective interior surfaces of a lower part of each of the arms. An XY probe 74 is slidably adjustably received through an opening in an extension part 75 of the slider, this probe 74 having at its lower end a semi-circular contact member 76 to engage the femur as shown in Figure 3. Whilst this embodiment includes, like the first

embodiment, a sighting disc 77, this disc is, in this embodiment, received on the end of the circular rod of the probe 74 as shown in Figure 3, so that it lies on the extension part 75 and extends to the top of the adjustment member 62 so that, as shown in Figure 3, it can be in abutting relationship with the outer surface of the flange 67.

In operation, this second embodiment functions in the following manner.

Firstly the one-piece base part 57 is placed on the femoral head so that it lies approximately on the chosen axis. The base part 57 will have at least two or more fixed spikes or studs, with a profile that allows sufficient anchorage into the bone, without having an adverse effect on the fixation of the prosthesis. As with the first embodiment, the application and removal of the base part will be by means of a separate drift tool (not shown). Once the base part has been secured in position, the adjustment member 62 is placed on the top surface thereof, and magnetically adheres thereto as mentioned above. The Surgeon will position the adjustment member 62 to provide appropriate angular position. As with the first embodiment, the spherically adjusted angular position of the adjustment member can be tested with a protractor device (not shown) inserted into the opening 63 of the adjustment member 62. When the Surgeon is satisfied with the angular positioning of the adjustment member 62, the cannula guide 66 will be placed onto the upper surface of the adjustment member 62, as shown in Figure 3, and the cannula guide will thus magnetically adhere to the upper planar surface of the adjustment member 62.

As with the first embodiment, the Surgeon then applies the slider 71 and probe 74 at the groove 65 to determine the optimum position of the cannula guide in one plane. With this embodiment however, the sighting disc 77 is applied to the probe 74 as shown in Figure 3. Alternative sizes of sighting disc 77 can be used depending on the size of prosthesis to be fitted. As shown in Figure 3, the contact member 76 is at a lower part of the femoral head as compared with its position as shown in Figure 1 in the previous embodiment, although this is not a significant difference in that the probe will be used on various points of the head, and/or the neck, of the femur. Again the slider can be rotated in its groove 65 in order to make similar adjustments in alternative planes. Also again, the sighting disc and probe can be used to determine if any incremental adjustment of the guide 66 is required.

When the Surgeon is satisfied with the positioning of the cannula guide, then the pivot rod 69 is inserted into the bore 68 of the cannula guide and pushed down into the surface of the bone to provide additional support as described above. It is then possible to proceed accurately with the insertion of the guide wire through the fine bore 70 in the pivot rod.

Accordingly in both embodiments the accuracy of location of the wire drill guide, and thus ultimately of the drilling, is improved.

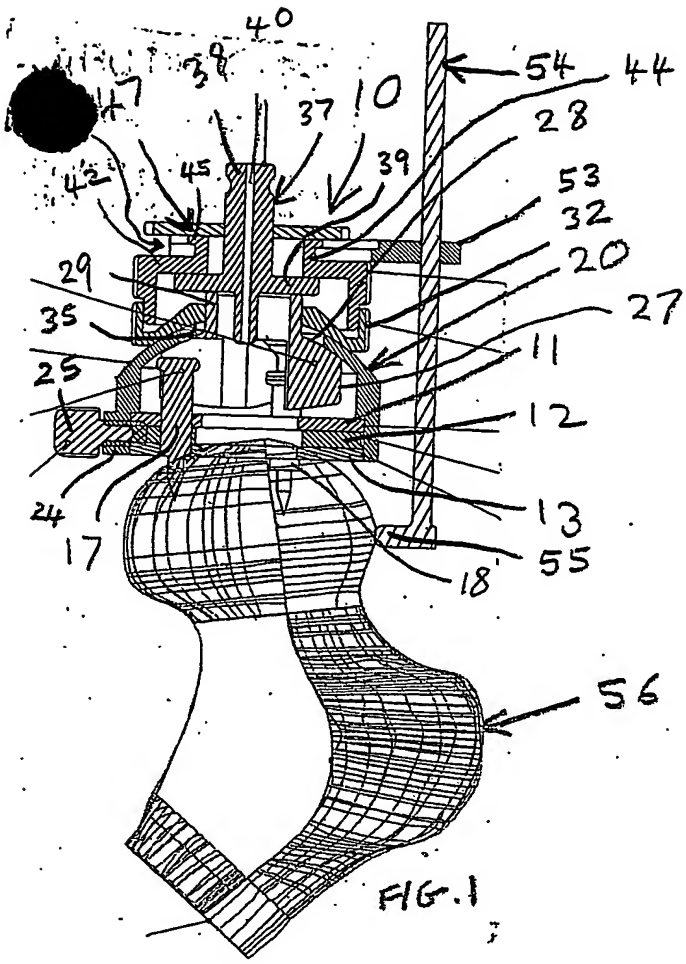


FIG. 1

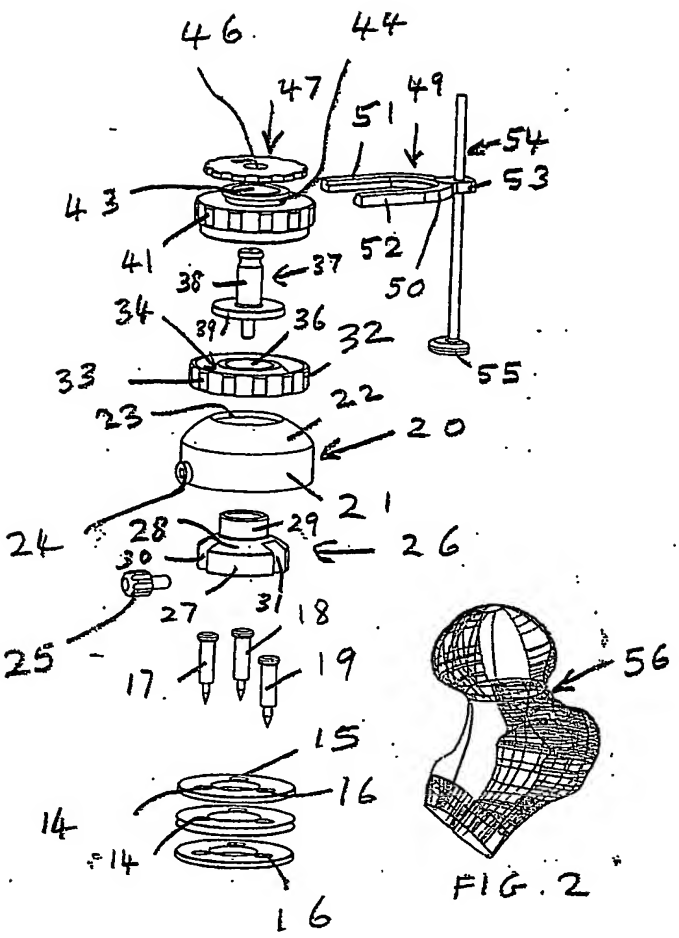
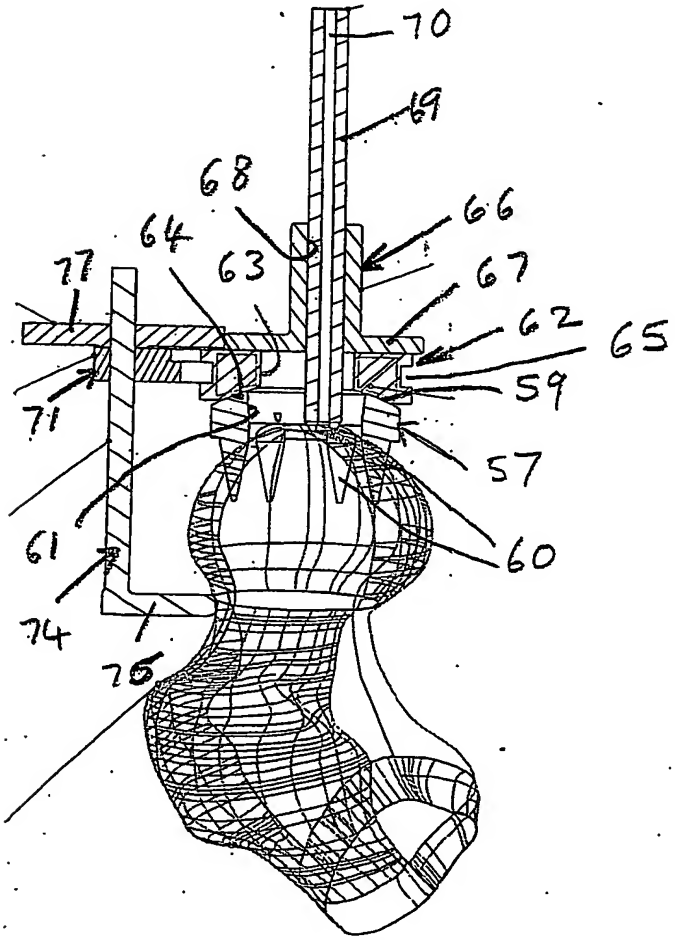


FIG. 2



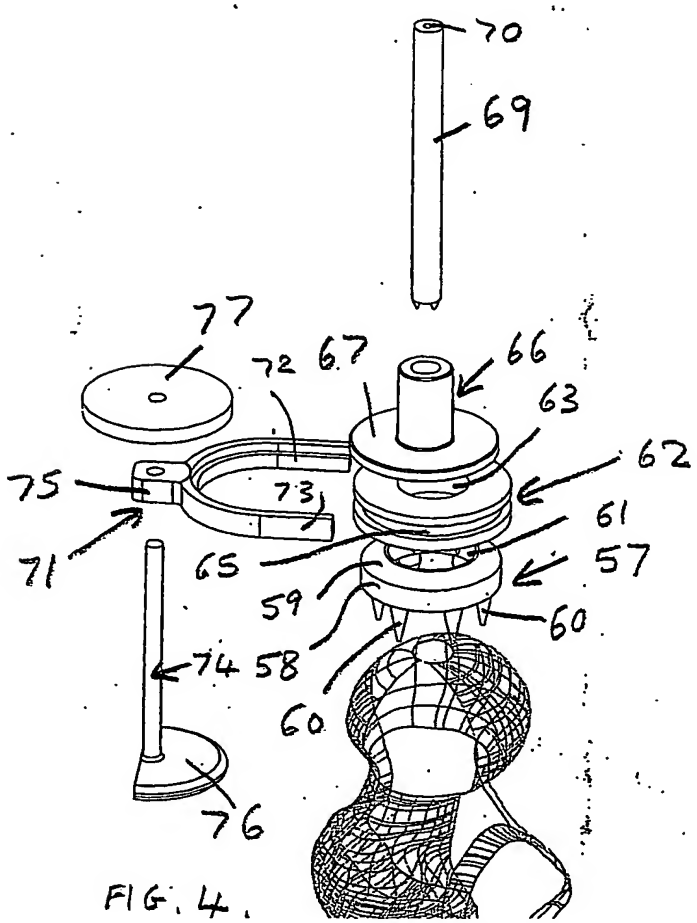


FIG. 4.

PCT/GB2004/002531